



Geoffrey W. Castello

Kelley Drye & Warren LLP
One Jefferson Road
Parsippany, NJ 07054

Tel: (973) 503-5922
Fax: (973) 503-5950
gcastello@kelleydrye.com

March 6, 2024

Via ECF

Hon. Louis L. Stanton, U.S.D.J.
United States District Court
Southern District of New York
500 Pearl Street
New York, NY 10007

Re: *FTC, et al. v. Quincy Bioscience Holding Co., Inc., et al.*,
Case No. 1:17-cv-00124-LLS

Your Honor:

We write on behalf of Defendants in response to a letter filed by Plaintiff NYAG yesterday, March 5, 2024, ECF No. 417 (the “NYAG Letter”), related to Defendants’ proposed jury instructions, ECF No. 384 (“Defs.’ PJI”), and verdict form, ECF No. 399-1 (“Defs.’ PVF”).

Burden of Proof. Contrary to the NYAG’s contentions, the NYAG has the burden of proof for every element of its claims against Quincy. The NYAG fails to cite any cases regarding the NYAG’s New York law claims, *i.e.*, the only claims at issue before the jury. Instead, the NYAG focuses solely on the burden of proof for the claims brought under Section 5 of the Federal Trade Commission Act (the “FTC Act”) and attempts to adopt that burden of proof as its own. (*See* ECF No. 417 at 1 (citing cases litigated by the Federal Trade Commission under the FTC Act).) That is improper.¹ As this Court instructed on the first day of trial, “[t]his case has *two* phases. The first phase is this jury trial between New York State by its Attorney General and Quincy, and you [are] on that jury. The second phase involves the Federal Trade Commission and you’ll have no concern with that matter and *should put it out of your mind.*” Trial Tr. at 7:13-18 (emphasis added). It would be improper to instruct the jury on the FTC Act or the burden of proof under those claims. Defendants’ proposed jury instructions and verdict form

¹ The NYAG’s suggestion that the FTC Act is given “great weight” in construing applicable New York law is limited to the *substance* of FTC Act claims, *i.e.*, whether the challenged marketing claims are false, misleading, or adequately substantiated. This is made clear by the cases the NYAG cites in support, which do not in any way stand for the proposition that the FTC Act’s *burden of proof* is adopted by New York law. In *State v. Feldman*, the Court overviews the pleading standards for GBL § 349 *under New York law*, not the FTC Act. 210 F. Supp. 2d 294, 300-01 (S.D.N.Y. 2002). And in *In re People v. Applied Card Systems, Inc.*, the Court makes clear that the FTC Act is “*useful*” to understand New York statutes, not that it stands as a replacement for them. 27 A.D.3d 104, 106-07 (3d Dep’t 2005), *aff’d on other grounds*, 11 N.Y.3d 105 (2008) (emphasis added).

March 6, 2024

properly focus on the NYAG's burden of proof *under New York law*, and that standard should be adopted by this Court. (See Defs.' PJI No. 7; Defs.' PVF.)

Even if the Court were to adopt the burden of proof applicable to claims under Section 5 of the FTC Act (and it should not), the NYAG misstates the burden of proof that would be applicable here. First, the NYAG fails to acknowledge that, under the FTC Act, it would be the NYAG's initial burden to prove that Quincy "lacked a reasonable basis for asserting the challenged claim." See *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006). Second, and critically, it is undisputed that Quincy has presented the substantiation for its claims—*in vitro* studies, animal studies, and human studies on apoaequorin, along with substantial evidence about Vitamin D—which has all been received in evidence. Therefore, it is unnecessary to present any instructions to the jury related to Defendants' alleged burden to "establish[] the substantiation it relied on for its claim." *Id.* Accordingly, any relevant burden of proof is *solely* on the NYAG, which must prove that the claims at issue are *not* supported by competent and reliable scientific evidence and were likely to mislead a reasonable consumer. *Id.*

Monetary Relief: Defendants acknowledge this Court's ruling on the motion *in limine* regarding reference to monetary relief sought by the NYAG, and agrees that reference to that relief is unnecessary.

General Business Law §§ 349 and 350: Contrary to the NYAG's assertions, Defendants' proposed jury instructions correctly set forth the elements of the NYAG's claims under GBL §§ 349 and 350. The NYAG appears to argue that different standards of proof apply depending on whether private plaintiffs or the NYAG brings claims pursuant to GBL §§ 349 and 350. But that is not the case. The NYAG cites cases brought by the NYAG and private plaintiffs interchangeably when discussing the standards for claims under GBL §§ 349 and 350. (See ECF No. 417 at 2 (first citing *Plavin v. Grp. Health Inc.*, 35 N.Y.3d 1 (2020) (private plaintiffs); then citing *Goshen v. Mut. Life Ins. Co.*, 98 N.Y.2d 314 (2002) (NYAG); and then citing *People v. Gen. Elec. Co.*, 302 A.D.2d 314, 315 (1st Dep't 2003) (NYAG)). Defendants acknowledge that the NYAG may seek relief under GBL § 349 without a showing of injury. But as *the NYAG's own citation makes clear*, the other pleading requirements for GBL § 349 remain the same. See *Gen. Elec. Co.*, 302 A.D.2d at 315 ("the plaintiff must prove that the challenged act or practice was misleading in a material way and the deceptive practice must be likely to mislead a reasonable consumer acting reasonably under the circumstances."). On its face, that standard requires a showing that the "deceptive practice" at issue was consumer oriented (as it must have been likely to mislead a reasonable *consumer*) and that it *was* misleading in a material way, as was reflected in Defendants' proposed jury instructions. (See Defs.' PJI No. 20-22.)

Of greatest concern is the fact that the NYAG's alleged "standard of proof" for claims under GBL §§ 349 and 350 entirely misstates the controlling standard. See *Plavin*, 35 N.Y.3d at 9-10; *Gen Elec. Co.*, 302 A.D.2d at 315, *Goshen*, 98 N.Y.2d at 324. As the Court of Appeals has recently confirmed, "to state a claim under §§ 349 or 350 a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice." *Plavin*, 35 N.Y.3d at 9-10. Nowhere does the Court indicate that the representations at issue need only have "the capacity to" mislead or deceive; in fact, the standard clearly states otherwise. See *id.* (statement "is" materially misleading); *Goshen*, 98 N.Y.2d at 324 (requires "a showing that defendant is engaging in an act or practice that is deceptive or misleading in a material way")

March 6, 2024

(emphasis added); *see also* N.Y. Pattern Jury Inst. 3:20.2 (standard jury instructions for claims under GBL §§ 349 and 350). Accordingly, the NYAG's arguments are contrary to law, and should be ignored.

Implied Claims: The NYAG's argument—premised on a single, non-binding Seventh Circuit case (not decided under New York law)—fails to acknowledge the support for Defendants' position that implied claims are claims that are "susceptible to more than one reasonable interpretation," not merely claims that are "oblique or indirect." *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 525 (S.D.N.Y. 2009) (interpreting "indirect claim" in assessing claim under the Lanham Act); *see also Naked Cowboy v. CBS*, 844 F. Supp. 2d 510, 518 (S.D.N.Y. 2012) ("The standards under [GBL §§ 349 and 350] are substantially the same as those applied to claims brought under Section 43(a) of the Lanham Act."). And Defendants wholly disagree that all of the claims at issue are "express or clearly and conspicuously implied," as the NYAG argues. (ECF No. 370 at 9.) Defendants respectfully acknowledge this Court's ruling that Defendants are not permitted to argue that evidence of consumer perception is required, but assert that the jury should be given the opportunity to assess whether a reasonable consumer—those at issue under New York law—could have other, reasonable interpretations of the claim at issue (which, in turn, would mean that such claims are not materially misleading and do not violate GBL §§ 349 and 350). *See Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y. 20, 26 (1995) (acknowledging "the adoption of an objective definition of deceptive acts and practices, whether representations or omissions, limited to those likely to mislead a reasonable consumer acting reasonably under the circumstances").

Disclaimers: Defendants maintain that the instruction provided related to disclaimers adequately communicates controlling law. The NYAG's contrary position is wholly unsupported.

Compliance with Federal Law: The NYAG's position that the safe harbor defense contained in GBL §§ 349(d) and 350 does not apply because of the bifurcation of the NYAG and FTC's claims defies logic and law. As stated more fully in Defendants' summary judgment briefing, the GBL §§ 349(d) and 350 establish a "complete defense" where the challenged actions comply with federal law, and have dismissed claims using that defense. (*See* ECF 227 at 44-45.) Indeed, this Court has acknowledged the safe harbor defense—and the jury's role in ensuring its application here—on the record. *See* Trial Tr. at 1125:5-11 ("For the jury, let me just explain to you very briefly the importance of this topic in this case. It is because the law of the state of New York, which applies in this case, prosecuted by the Attorney General, that it is a complete defense to claims that the laws have not been complied with, that there was a scientifically substantial basis for the claims made."). Accordingly, the NYAG's position regarding the safe harbor defense under GBL §§ 349 and 350 should be rejected.

Application of Dietary Supplement Health and Education Act ("DSHEA"): The trial developed in such a way that Defendants agree that it is no longer necessary to include an instruction relating to DSHEA.

Application of FTC Dietary Supplement Guide: Once again, the NYAG's positions on the FTC Guidance miss the mark. In order to succeed on its claims, the NYAG has the burden to prove that Quincy's substantiation for its claims is insufficient. And, as this Court has made clear, the proper instruction to the jury on this point is that the FTC Guidance "is not another source of the law. It is,

March 6, 2024

however, an explanation by the authorities in the field about how to comply with the law. And that is not stating the law. It's a statement making it easier and sound to comply with it." (Trial Tr. at 1131:12-16.)

New York Executive Law § 63(12): Defendants maintain that N.Y. Exec. Law 63(12) does not create a standalone cause of action, and that Defendants' instructions related to N.Y. Exec. Law 63(12) are proper. The NYAG's position that it is "well established" that N.Y. Exec. Law 63(12) provides a standalone cause of action is belied by *countervailing case law* on this very issue. *See People ex. rel. Schneiderman v. One Source Networking, Inc.*, 125 A.D.3d 1354, 1355-56 (4th Dep't 2015) (holding that section 63(12) "does not create an independent cause of action" as "that section is only a mechanism by which a petitioner may show that injunctive relief and restitution are proper in the event that the petitioner established that a respondent violated other statutes"); *see also City of New York v. Fedex Ground Package Sys., Inc.*, 175 F. Supp. 3d 351 (S.D.N.Y. 2016) (dismissing claim brought under N.Y. Exec. Law 63(12) where plaintiff failed to plead adequate cause of action under claim brought under NYPHL § 1399-ll because N.Y. Exec. Law 63(12) allows the NYAG to seek penalties "via the penalty provision of any underlying statute" (emphasis added) (citations omitted)). In light of this precedent, the NYAG's claims under N.Y. Exec. Law 63(12) rise and fall with its claims under GBL §§ 349 and 350, and separate instructions on N.Y. Exec. Law 63(12) are accordingly unnecessary.²

Defendants further maintain that the NYAG's instructions related to N.Y. Exec. Law 63(12) reference an inapplicable standard of review. Specifically, the NYAG maintains that representations are actionable where they "had the capacity or tendency to deceive not only the average consumer, but also the ignorant, the unthinking, and the credulous, or created an atmosphere conducive to fraud." ECF No. 387 at 23, 28. But that standard arises from *Guggenheimer v. Ginzburg*, 43 N.Y.2d 268, 273 (1977). New York courts have long since abandoned *Guggenheimer* standard in favor of the "reasonable consumer" standard discussed above. *See In re Hollander*, No. 160972/13, 2015 N.Y. Misc. LEXIS 2317, at *9-10 n.2 (Sup. Ct. N.Y. 2015) ("Although not explicitly overruled, the Court of Appeals appears to have retreated from its earlier pronouncement in *Guggenheimer v. Ginzburg*, 43 N.Y. 2d 268, 273 (1977)." (first citing *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995); and then citing *Gaidon v. Mutual Life Ins. Co. of Am.*, 94 N.Y.2d 330, 353 (1999))). The Second Circuit *also* follows the reasonable consumer standard as set forth in Defendants' PJI and PVF. *See Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013). The NYAG's position—and its consistent citation of *Guggenheimer* in support—relies on an abandoned principle of law and should be ignored.

Rule 50(a). Defendants intend to renew their Rule 50(a) motion for judgment as a matter of law at the start of the charge conference. In addition to the grounds previously raised, Defendants intend to

² Even if N.Y. Exec. Law 63(12) creates an independent cause of action (it does not), the statute's text makes clear that such cause of action is only applicable in limited circumstances not present here. N.Y. Exec. Law 63(12) allows the NYAG to call for summary proceedings before the Supreme Court of the State of New York on *five days'* notice. *See also People by James v. Northern Leasing Systems, Inc.*, 193 A.D.3d 67 (1st Dep't 2021) ("A special proceeding, as authorized by Executive Law § 63(12), is intended as an expeditious means for the Attorney General to prevent further injury and seek relief for the victims of business fraud." (citations omitted)). As this Court is well aware, that is not applicable here, where the NYAG brought its claims alongside GBL §§ 349 and 350 claims, in federal court, has been litigating those claims for over *seven (7) years*, and has never sought an injunction or restraining order.

March 6, 2024

move for partial judgment as a matter of law with regards to all claims related to the version of Prevagen that contains Vitamin D. The NYAG has failed to meet their burden of production as to whether there is competent and reliable scientific evidence that supports the Challenged Claims for the version of Prevagen that contains Vitamin D, which has been present in Prevagen's formulation since 2016.

The NYAG presented Dr. Sano as their sole expert witness regarding the issue of whether there was competent and reliable scientific evidence that Vitamin D improves memory and cognition. In just three pages of the trial transcript, Trial Tr. at 291-293, Dr. Sano opined that she had reviewed "meta analyses and other systematic review as well as clinical trials" relevant to Vitamin D's effect on memory and cognition, and concluded that those specific studies were not competent and reliable scientific evidence of an effect of Vitamin D on memory or cognition in the general population. Trial Tr. at 291:11-16.

But Dr. Sano explicitly stated that her opinion was subject to a "qualification" that she was "talk[ing] about [the] general public without talking about a Vitamin D deficient population." Trial Tr. at 322:1-323:3. However, Dr. Kurzer testified that "national surveys carried out by the federal government [indicate] that about 42 percent of the U.S. population is deficient in vitamin D, a really extremely high percentage. And when you look at certain subgroups, African Americans are 80 percent deficient and Hispanic Americans are 70 percent deficient. So the deficiency is actually even greater in particular subgroups of people." (Trial Tr. at 1007:25-1008:8.) Dr. Kurzer concluded that competent and reliable scientific evidence supported the challenged claims with regards to Vitamin D. (Trial Tr. at 1010:21-24, 1011:25-1012:3, 1015:6-16.) This testimony was undisputed by either Dr. Sano or *any other witness*. Accordingly, Dr. Sano offered no opinion as to whether competent and reliable scientific evidence supported the challenged claims as to the nearly half of the U.S. population with Vitamin D deficiencies.

Thus, no reasonable jury could conclude that Dr. Sano's limited opinion, which ignores the very half of the U.S. population that most needs a dietary supplement containing Vitamin D, is sufficient to find that no competent and reliable scientific evidence supports claims that Prevagen can improve memory and cognition. At most, a reasonable jury *may* be able to conclude that there is no competent and reliable scientific evidence that Vitamin D has a therapeutic effect on memory and cognition in the significant portion of the U.S. population without a Vitamin D deficiency. But that is not enough. Given the limited scope of Dr. Sano's opinion, the NYAG has failed to produce *any* evidence contradicting Dr. Kurzer's conclusions. Standing alone, this would require any reasonable jury to find in Defendants' favor with respect to all claims related to the version of Prevagen that contains Vitamin D. Accordingly, Defendants intend to respectfully request that the Court grant partial judgment as a matter of law with regards to such claims.

March 6, 2024

Respectfully submitted,

KELLEY DRYE & WARREN LLP

COZEN O'CONNOR, P.C.

By: /s/ Geoffrey W. Castello

John E. Villafranco (admitted pro hac vice)
Geoffrey W. Castello
William A. Escobar
Jaclyn M. Metzinger
Glenn T. Graham
Caitlin R. Hickey
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 808-7800
Fax: (212) 808-7897
jvillafranco@kelleydrye.com
gcastello@kelleydrye.com
jmetzinger@kelleydrye.com
ggraham@kelleydrye.com
chickey@kelleydrye.com

*Counsel for Defendants Quincy Bioscience
Holding Company, Inc., Quincy Bioscience,
LLC, Prevagen, Inc. d/b/a Sugar River
Supplements, and Quincy Bioscience
Manufacturing, LLC*

By: /s/ Michael B. de Leeuw

Michael B. de Leeuw
Tamar S. Wise
Amanda Giglio
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (212) 908-1331
mdeleeuw@cozen.com
twise@cozen.com
agiglio@cozen.com

Robert S. Clark
1650 Market Street, Suite 2800
Philadelphia, PA 19103
Tel: (215) 665-2041
robertclark@cozen.com

Counsel for Defendant Mark Underwood